PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.:	10/659,490	Confirmation No.:	3452
Applicant	: Robert B. DeVries		
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TC/A.U.	: 3731		
Examiner	: Lang, Amy T.		
Title	: COMPOSITE MEDICAL DEVICES		
Docket No.	: 1001.1602101		
Customer No.	: 28075		

APPEAL BRIEF FILED UNDER 37 C.F.R. § 41.37

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By JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on March 24, 2010, and of the Notice of Panel Decision from Pre-Appeal Review dated mailed June 8, 2010. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One Scimed Place, Maple Grove, MN 55311-1566. An assignment from the inventors, Robert B. DeVries, Kristian DiMateo and Steven Walak, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014478, Frame 0824. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 016060, Frame 0557.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-69 are pending in the application. Claims 11-64 have been withdrawn from the application.

Claims 1-4, 6-10, and 65-69 stand finally rejected under 35 U.S.C. § 102(b) as being unpatentable over Tomonto, U.S. Patent No. 6,425,855.

Claim 5 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Tomonto, U.S. Patent No. 6,425,855, in view of Moore, U.S. Published Patent Application No. 2004/0024444.

Claims 1-10 and 65-69 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

Claims 1, 67, and 68 were amended subsequent the final rejection of November 30, 2009. The Examiner entered the amendments for the purpose of appeal. Claims 67 and 68 were amended in response to a suggestion by the Examiner.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The present invention relates generally to devices implantable within a body lumen. More specifically, the present invention pertains to composite medical devices implantable within a body vessel, for example a vena cava filter as illustrated in Fig. 10.

Turning now to independent claim 1, which is directed to composite medical device (see, for example, specification page 1, lines 10-14), comprising: a first composite elongated member (see, for example, specification page 1, line 24 to page 2, line 21, page 6, lines 4-22, page 7, line 1 to page 12, line 11, page 14, lines 4-11, page 14, line 13 to page 16, line 19; Figs. 1-10 and 15-17; reference numerals 18, 118, 218, 318, 412) formed from an outer member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, line 12 to page 6, line 2, page 7, line 22 to page 8, line 10, page 10, lines 6-22, page 11, lines 12-14, page 12, line 12 to page 13, line 19, page 15, lines 6-20, page 16, lines 6- 17; Figs. 3, 4, 6, 7, 9, 11-14, 16, 17; reference numerals 26, 48,130, 226, 424) comprising a first material (see, for example, specification page 1, line 24 to page 2, line 3, page 5, lines 15-18, page 7, line 22 to page 8, line 2, page 10, lines 3-6, page 15, lines 6-8) and an inner member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, lines 12-21, page 7, line 22 to page 8, line 3, page 10, lines 3-16, page 11, lines 12-14, page 12, line 12 to page 14, line 3, page 15, line 6 to page 16, line 17, page 17, lines 3-4; Figs. 3, 4, 6, 7, 9, 11-4, 16, 17; reference numerals 28, 50, 132, 228, 424, 426) comprising a second material (see, for example, specification page 1, line 24 to page 2, line 3, page 5, lines 15-18, page 7, line 22 to page 8, line 10, page 10, lines 3-6, page 15, lines 6-20) different from the first material (see, for example, specification page 1, line 24 to page 2, line 3, page 5, lines 15-18, page 7, line 22 to page 8, line 2, page 10, lines 3-6, page 15, lines 6-8), the outer member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, line 12 to page 6, line 2, page 7, line 22 to page 8, line 10, page 10, lines 6-22, page 11, lines 12-14, page 12, line 12 to page 13, line 19, page 15, lines 6-20, page 16, lines 6- 17; Figs. 3, 4, 6, 7, 9, 11-14, 16, 17; reference numerals 26, 48,130, 226, 424) surrounding and encasing the inner member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, lines 12-21, page 7, line 22 to page 8, line 3,

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting as support may be found throughout the specification and in many of the Figures.

page 10, lines 3-16, page 11, lines 12-14, page 12, line 12 to page 14, line 3, page 15, line 6 to page 16, line 17, page 17, lines 3-4;Figs. 3, 4, 6, 7, 9, 11-4, 16, 17; reference numerals 28, 50, 132, 228, 424, 426), wherein the second material (see, for example, specification page 1, line 24 to page 2, line 3, page 5, lines 15-18, page 7, line 22 to page 8, line 10, page 10, lines 3-6, page 15, lines 6-20) is more elastic than the first material (see, for example, specification page 1, line 24 to page 2, line 3, page 5, lines 15-18, page 7, line 22 to page 8, line 2, page 10, lines 3-6, page 15, lines 6-8); and at least one flexibility region (see, for example, specification page 2, line 8 to page 3, line 9, page 5, line 21 to page 6, line 1 and lines 16-22, page 9, lines 10-22, page 11, lines 1-17, page 12, lines 3-18 and 21 to page 13, line 18, page 16, lines 6-11; Figs. 1, 5, 8-10, 17, ; reference numeral 22, 122, 238, 322, 338, 430) formed on said first composite elongated member (see, for example, specification page 1, line 24 to page 2, line 21, page 6, lines 4-22, page 7, line 1 to page 12, line 11, page 14, lines 4-11, page 14, line 13 to page 16, line 19; Figs. 1-10 and 15-17; reference numerals 18, 118, 218, 318, 412), said flexibility region (see, for example, specification page 2, line 8 to page 3, line 9, page 5, line 21 to page 6, line 1 and lines 16-22, page 9, lines 10-22, page 11, lines 1-17, page 12, lines 3-18 and 21 to page 13, line 18, page 16, lines 6-11; Figs. 1, 5, 8-10, 17, ; reference numeral 22, 122, 238, 322, 338, 430) formed by selectively removing a portion of the outer member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, line 12 to page 6, line 2, page 7, line 22 to page 8, line 10, page 10, lines 6-22, page 11, lines 12-14, page 12, line 12 to page 13, line 19, page 15, lines 6-20, page 16, lines 6- 17; Figs. 3, 4, 6, 7, 9, 11-14, 16, 17; reference numerals 26, 48,130, 226, 424) to expose the inner member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, lines 12-21, page 7, line 22 to page 8, line 3, page 10, lines 3-16, page 11, lines 12-14, page 12, line 12 to page 14, line 3, page 15, line 6 to page 16, line 17, page 17, lines 3-4;Figs. 3, 4, 6, 7, 9, 11-4, 16, 17; reference numerals 28, 50, 132, 228, 424, 426), wherein, when the composite medical device (see, for example, specification page 1, lines 10-14) is deformed about the exposed inner member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, lines 12-21, page 7, line 22 to page 8, line 3, page 10, lines 3-16, page 11, lines 12-14, page 12, line 12 to page 14, line 3, page 15, line 6 to page 16, line 17, page 17, lines 3-4;Figs. 3, 4, 6, 7, 9, 11-4, 16, 17; reference numerals 28, 50, 132, 228, 424, 426)

from a first position to a second position, the exposed inner member (see, for example, specification page 1, line 24 to page 3, line 4, page 5, lines 12-21, page 7, line 22 to page 8, line 3, page 10, lines 3-16, page 11, lines 12-14, page 12, line 12 to page 14, line 3, page 15, line 6 to page 16, line 17, page 17, lines 3-4;Figs. 3, 4, 6, 7, 9, 11-4, 16, 17; reference numerals 28, 50, 132, 228, 424, 426) tends to bias the medical device (see, for example, specification page 1, lines 10-14) toward the first position, wherein said first composite elongated member (see, for example, specification page 1, line 24 to page 2, line 21, page 6, lines 4-22, page 7, line 1 to page 12, line 11, page 14, lines 4-11, page 14, line 13 to page 16, line 19; Figs. 1-10 and 15-17; reference numerals 18, 118, 218, 318, 412) has a solid cross-section.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-4, 6-10, and 65-69 are patentable over Tomonto, U.S. Patent No. 6,425,855, under 35 U.S.C. § 102(b).

Whether claim 5 is patentable over Tomonto, U.S. Patent No. 6,425,855, in view of Moore, U.S. Published Patent Application No. 2004/0024444, under 35 U.S.C. § 103(a).

VII. ARGUMENT

A. CLAIMS 1-4, 6-10, AND 65-69 ARE PATENTABLE OVER TOMONTO, U.S. PATENT NO. 6,425,855, UNDER 35 U.S.C. § 102(b).

1. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

With regard to the rejection of claims 1-4, 6-10, and 65-69 over Tomonto, a primary issue and a secondary issue remain to be resolved. It is Appellants' position that one of ordinary skill in the art would interpret the claim phrase "the outer member surrounding and encasing the inner member" in view of the specification and drawings as the outer member contacting the inner member on all sides.

The Examiner has clearly erred by attempting to assert that the claim phrase may be given alternate interpretation(s) which are inconsistent with the specification and drawings.

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). 37 CFR 1.75(d)(1). (Emphasis Added.)

As seen in the Figures and sketches below, in each embodiment the members in question are wires or, equivalently, solid cross-section members formed by combining tubular elements which are "swaged and drawn, forming a metallurgical bond between the different materials". (See page 16, lines 14-21.) As such, outer materials surround the inner material(s) to form the solid cross-section member claimed prior to selective removal of the outer material to fully expose the inner material.

Relevant figures are reproduced below for convenience:

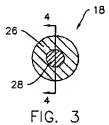


FIG. 3

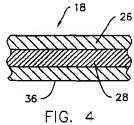


FIG. 4

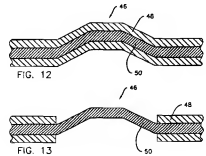
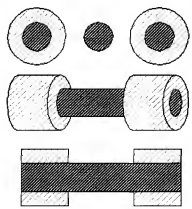


FIG. 12

FIG. 13

The following sketches provide additional views of exemplary wires to which several cross-sections and a semi-perspective view have been added.



Pertinent figures of Tomonto are presented below:

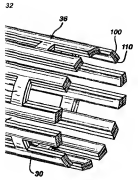


Fig. 1 (Detail)

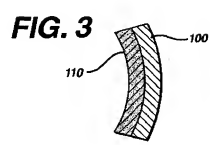


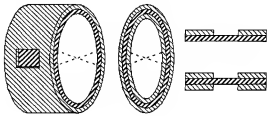
Fig. 3 of Tomonto depicts a cross-section of a laminated tubular stent structure of Tomonto's title, said laminate stent being illustrated in Fig. 1 as cut from a bilayer tube where lamella 100 and adjacent lamella 110 are labeled at upper right. As will be seen immediately in Fig. 3, layer 100 of graft 30 neither "surrounds" nor "encases" layer 110 in the sense used in the pending claim 1 and throughout the pending specification, but rather contacts said layer 110 on, at most, only one of four sides. Within the cited Figure 1 of Tomonto, the Examiner has identified, at page 8 of the Final Office Action, portions of relieved generally cylindrical grafts 20 and 30 as "First Strut" and other portions of the same cylindrical grafts 20 and 30 as "Second Strut" without indicating how those cylindrical grafts 20 and 30 are considered to form struts. It remains unclear what structure within Tomonto is asserted to correspond to an elongated member of the claims.

The Examiner has erred in arguing: "Additionally, as shown in Figure 1, the outer layer is external to and directly attached to the inner layer on multiple sides so that the outer layer clearly surrounds the inner layer." (Emphasis added by Appellants. See graft 30 detail from Fig. 1 reproduced above.) Figure 3 illustrates "a partial cross sectional view of the stent in Fig. 2 taken along line 3-3." In each cross-section of the stent of Fig. 1 in which a portion of a graft 20 or 30 appears as a solid member, layer 110 is exposed on at least three sides as illustrated in Fig. 3. Fig. 2, of which Fig. 3 represents a section, differs form Fig. 1 only in that a third graft 40 has been added to lengthen the stent. Although related Fig. 1 is believed to confirm, in the end view detail presented above, that within a strut (52, 62) or graft (20, 30, 40) of the stent of Tomonto, which might correspond to a wire of the pending specification, layer 100 lies adjacent and parallel to

layer 110 contacting said layer only on a single surface, Appellants have also previously addressed a somewhat different interpretation of the disclosure of Tomonto to which the Examiner may have been referring.

Comments by the Examiner appear to have asserted that since the stent of Tomonto may be formed from a hollow two layer laminated tube similar to that in the sketch below left, layer 100 of the tube is everywhere external to layer 110 of the precursor tube from which the strut is formed and so in some sense the tube of material 100 may surround the tube of material 110 by merely abutting the exterior thereof.

Illustrative cross-sectional sketches are:



The claim, however, recites that the "composite elongated member has a solid cross-section" and an outer member must "surround" the inner member within the composite elongated members comprising the stent rather than within the stent as a whole or a tubular precursor from which the stent is eventually formed. In the stent as a whole, traversing the stent along the dotted lines in the sketch at left above demonstrates that, for the stent as a whole, the body is hollow and not solid. Traversing the stent body, one encounters in sequence layer 100, layer 110, air, layer 110, and layer 100. Further, for struts cut from such a body no component layer of a strut is "surrounded" as there are always at least two exposed sides along the cut edges of layer 110 as well as the typically exposed inner surface.

The Examiner's position as presented in the Advisory Action is that "to surround or encase may not limit to a complete enclosure. Surround is also defined as to enclose and to enclose is defined as to hold in (Merriam-Webster)." The Examiner errs in applying the descriptors to the composite medical device of Tomonto as a whole rather than to the solid elongate members as recited in claim 1. It should be noted that the Examiner's ability to find a chain of definitions which may support an alternate

interpretation of a claim is not the standard to be applied in claim interpretation, rather it is the interpretation of one of ordinary skill in the art in view of the specification which applies. Further, even the Examiner's selection of a synonym for surround as: "enclose" is qualified in the cited definition as "to enclose on all sides" and "to enclose so as to cut off communication" when the full dictionary entry is considered.

> surround:
> Function: transitive verb
> **1a** (1) : to enclose on all sides : envelop <the crowd surrounded her> (2) : to enclose so as to cut off communication or retreat : invest
> **b** : to form or be a member of the entourage of <flatterers who surround the king>
> **c** : to constitute part of the environment of <surrounded by poverty>
> **d** : to extend around the margin or edge of : encircle
> (Merriam-Webster's Online Dictionary, 11th Edition; June 21, 2010)
> (Emphasis added.)

A compendium of 37 dictionaries found at www.onelook.com on June 21, 2010 provided these additional definitions for surround:

> verb: extend on all sides of simultaneously; encircle
> verb: envelop completely

> If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. Brookhill-Wilk 1, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.")

Here, the context for the claim interpretation in question is provided throughout the specification and drawings. At no time is that context consistent with the Examiner's improper interpretation.

> Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if

other modes of expression selected by applicants satisfy the statutory requirement. (MPEP 2173.02)

The Examiner has also erroneously attempted to apply a secondary meaning of "enclose" in the sense of surround to the claim, again in an effort to direct attention away from the plain meaning of the terms as used in the pending specification and drawings and as those terms would be interpreted by one of ordinary skill in the art:

> enclose
> Function: transitive verb
> **1a** (1) : to close in : surround <enclose a porch with glass> (2) : to fence off (common land) for individual use b : to hold in : confine
> **2** : to include along with something else in a parcel or envelope <a check is enclosed herewith>
> (*Ibid.*) (Emphasis added.)

Turning to the summary of 29 dictionary entries found at www.onelook.com for enclose:

> verb: close in or confine
> verb: surround completely
> verb: introduce
> verb: enclose or enfold completely with or as if with a covering

One finds that the preponderance of dictionary entries are consistent with the complete enclosure or covering interpretation given to the claim terms above as well as with the specification and drawings as a whole.

The Examiner has also made reference to col. 4, lines 50-53 of Tomonto: "The stent could have more than two layers and still possess all the advantages of the present invention.", however that passage fails to explicitly disclose the location or extent of the additional layers. The tube construction most favorable to the Examiner's position while remaining consistent with the lamellar tubes disclosed by Tomonto appears to be the formation of the stent from a three layer laminate tube, as illustrated in the middle cross-sectional sketch above, from which it would be possible to cut a stent graft section along the dashed lines having the form at bottom right, said stent section providing an intermediate material 110 which contacts two adjacent material layers 100 of the strut on

two of four sides, but which still does not disclose an outer material "surrounding and encasing" an inner material as recited in claim 1.

A further issue to be resolved is whether Tomonto explicitly discloses:

> "a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first material, the outer member surrounding and encasing the inner member, wherein the second material is more elastic than the first material"

The disclosure of Tomonto at col. 4, lines 40-49:

> "The particular design of the present stent and its advantages are best understood by describing the materials the stent is made from and how the slots and articulations are cut therefrom. By referring to FIG. 3, stent 10 is made from a multi laminate hollow tube, or hypotube as it is often referred to by those skilled in the art, having at least two layers, wherein one layer is made from a plastically deformable material, such as stainless steel or titanium, and the inner layer is made from a superelastic material such as Nitinol."

Thus the disclosure of Tomonto appears to be limited to a stent cut from a multi laminate tube where one (outermost) layer of the tube is made from a plastically deformable material and a second material of an inner layer is a superelastic material.

Note that pending claim 1 is not limited to superelastic inner materials. The claim is directed to the relative elasticity of the materials forming adjacent generally concentric layers forming the wire or composite elongated member from which portions of the less elastic material have been removed to provide a region of greater flexibility.

Tomonto does appear to disclose a stent embodiment in which the plastically deformable layer has been chosen to be a stainless steel and the superelastic material is said to be a Nitinol, however Tomonto is silent with respect to the relative elasticity of the two materials and does not identify the materials or their processing history In sufficient detail to allow the comparison to be made. The Examiner has not substantiated her assertion that combination necessarily anticipates "wherein the second material is more elastic than the first material" as recited in claim 1 for at least the reason that Tomonto does not specify the compositions of the stainless steel or of the Nitinol, their

thermal annealing histories, work hardening histories, or the conditions used to test the "elasticity". Appellants do not dispute that some Nitinol materials are more elastic than some stainless steels, but rather only dispute the Examiner's assertion that the Tomonto discloses that relationship in a composite elongated member construction in which stainless steel surrounds Nitinol.

The Examiner has made a number of assertions regarding the relative mechanical properties of stainless steel and Nitinol. Initially, it should be noted that neither "stainless steel" nor "Nitinol" would be understood by one of ordinary skill in the art to specify a single chemical composition and further one of ordinary skill in the art would appreciate that the mechanical properties of any given composition of those materials depend upon both the mechanical and thermal history to which the sample has been subjected. This is especially true of Nitinol where the art relies upon processing to greatly alter the mechanical properties of an article fabricated therefrom.

There are over 150 grades of stainless steel as well as a variety of measures of "elasticity". For example, it is relatively easy to find literature values for modulus, "elasticity", for stainless steels which vary by a factor of 3. The Examiner has not cited any portion of Tomonto which discloses that the disclosed generic superelastic material is necessarily more elastic than a generic plastically deformable material, or even that the unspecified Nitinol is more elastic than the unspecified stainless steel for any given measure of elasticity.

Rather than relying upon the disclosure of the Tomonto reference, in the Advisory Action, the Examiner turned to a secondary reference, (Mansmann et al., USPPA 2009/0132047 which claims priority to a provisional application filed November 30, 2004, 1 year, 2 months and 20 days after the filing of the pending application) with the assertion that the reference "provides support that nitinol alloys are more flexible and elastic than stainless steel (see paragraph [0026])". The appropriate portion of that paragraph appears to be:

> "As mentioned above, various nitinol-type alloys are much more flexible and elastic than stainless steel and other metals used in surgery."

Aside from the inappropriate date of the reference, Mansmann et al. only comments on the elasticity of some "nitinol-type alloys" relative to an unspecified

stainless steel under unspecified conditions and so does not directly compare any nitinol to any stainless steel. Further, Manismann qualifies even that disclosure as:

> After the filing of PCT application WO 05/032426 but before its publication, it was realized by the inventors herein that a certain class of metal alloys, usually referred to as "nitinol" or "shape-memory alloys", may allow various enhancements to be provided in the design, construction, and use of implants for replacing cartilage.
> (Paragraph [0018]; emphasis added.)

suggesting that one of ordinary skill in the art was not aware of the properties discussed until after the priority date of the cited reference. Further still, Mansmann et al. also state:

> "During the decades that followed, other shape-memory alloys were developed with other ingredients. Even though nickel and/or titanium may not be present in some of those formulations, "nitinol" is still widely used (and is used herein) as a common name for any "shape-memory alloy" (which also can be referred to by the acronym SMA)."
> (Paragraph [0021]; emphasis added.)

which suggests references within Mansmann to the term "nitinol" or "nitinol-type" materials do not necessarily refer to alloys of nickel and/or titanium. This would appear to provide insufficient basis for the Examiner's apparent assertion that Nitinol alloys are inherently more elastic than stainless steels. More particularly, this very general disclosure does not support the assertion that the unspecified Nitinol disclosed by Tomonto is more elastic than the unspecified stainless steel of Tomonto.

Even were it to be the case that the two layer stent of Tomonto had been constructed of materials such that the outer tube of the precursor structure was less elastic than the inner layer of the precursor tube, Tomonto does not appear to expressly or inherently describe the structure recited in claim 1 as discussed above since the material of the outer layer does not "surround" or "encase" the inner layer as that claim term would be interpreted by one of ordinary skill in the art upon reading the pending specification and viewing the drawings.

For at least these reasons, Tomonto does not anticipate each and every element of claim 1 and Appellants respectfully request that the rejection be overruled.

2. *Conclusion.*

For similar reasons as well as others, claims 2-4, 6-10, and 65-69, which depend from claim 1, and include significant additional limitations, are believed to be not anticipated by Tomonto and Appellants respectfully request that the rejections be withdrawn.

B. CLAIM 5 IS PATENTABLE OVER TOMONTO, U.S. PATENT NO. 6,425,855, IN VIEW OF MOORE, U.S. PUBLISHED PATENT APPLICATION NO. 2004/0024444, UNDER 35 U.S.C. § 103(a).

1. *All words in a claim must be considered in judging the patentability of that claim against the prior art.*

Moore is asserted to disclose "a stent that preferably coated with a polymeric layer in order to minimize adverse interaction with the walls of the blood vessel or blood flowing through the vessel". Said polymeric coating is not a limitation of independent claim 1 and so the disclosure of Moore does not appear capable of overcoming the deficiencies of that claim as discussed above.

2. *If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.*

Claim 5, which depends from nonobvious independent claim 1, also is believed to be nonobvious and Appellants respectfully request that the rejection be overruled.

C. CONCLUSION

For the reasons stated above, claims 1-4, 6-10, and 65-69 are not anticipated by Tomonto; claim 5 is nonobvious over Tomonto in view of Moore; and the Examiner's

rejections of claims 1-10 and 65-69 under 35 U.S.C § 102 and § 103 should be overruled.

Respectfully submitted,

Date: July 6, 2010

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VIII. CLAIMS APPENDIX

1. A composite medical device, comprising:

a first composite elongated member formed from an outer member comprising a first material and an inner member comprising a second material different from the first material, the outer member surrounding and encasing the inner member, wherein the second material is more elastic than the first material; and

at least one flexibility region formed on said first composite elongated member, said flexibility region formed by selectively removing a portion of the outer member to expose the inner member, wherein, when the composite medical device is deformed about the exposed inner member from a first position to a second position, the exposed inner member tends to bias the medical device toward the first position, wherein said first composite elongated member has a solid cross-section.

2. The device of claim 1, wherein the first material is selected from the group of materials consisting of stainless steel, gold, molybdenum, platinum, titanium, tungsten, L605, MP35N, Ta-10W, 17-4PH, alloy steels, cobalt-chrome alloy, cobalt alloy, metal glass alloy, and refractory metal alloy.

3. The device of claim 1, wherein said second material comprises a shape-memory material.

4. The device of claim 1, wherein said second material comprises a superelastic material.

5. The device of claim 1, wherein said outer member further includes a polymeric coating.

6. The device of claim 1, wherein at least a portion of said outer member is electrically removed.

7. The device of claim 1, wherein at least a portion of said outer member is chemically removed.

8. The device of claim 1, wherein at least a portion of said outer member is mechanically removed.

9. The device of claim 1, wherein the composite medical device comprises an intravascular filter.

10. The device of claim 1, wherein the composite medical device comprises a stent or stent graft.

11. An intravascular filter device for placement within a body vessel, comprising:

a plurality of elongated legs each having a proximal end and a distal end, the elongated legs being secured together;

each of said plurality of elongated legs being formed of an outer member comprising a first material, and an inner member comprising a second material different from the first material.

12. The intravascular filter device of claim 11, wherein said plurality of elongated legs are rod members.

13. The intravascular filter device of claim 11, wherein said plurality of elongated legs are tubular members.

14. The intravascular filter device of claim 11, wherein said plurality of elongated legs are ribbon members.

15. (The intravascular filter device of claim 11, wherein said plurality of elongated legs are configured to expand from a substantially straight position to an outswept position when placed within the body vessel.

16. The intravascular filter device of claim 11, wherein at least a portion of the distal end of said outer member is removed.

17. The intravascular filter device of claim 11, wherein said first material includes a radiopaque material.

18. The intravascular filter device of claim 11, wherein the first material is selected from the group of materials consisting of stainless steel, gold, molybdenum, platinum, titanium, tungsten, Elgiloy, L605, MP35N, Ta-10W, 17-4PH, Aeromet 100, cobalt-chrome alloy, cobalt alloy, metal glass alloy, and refractory metal alloy.

19. The intravascular filter device of claim 11, wherein the inner member is more elastic than the outer member.

20. The intravascular filter device of claim 11, wherein said outer member further includes a polymeric coating.

21. The intravascular filter device of claim 11, wherein said second material comprises a shape-memory material.

22. The intravascular filter device of claim 11, wherein said second material comprises a superelastic material.

23. The intravascular filter device of claim 11, wherein each of said plurality of elongated legs includes a hook region configured to engage the walls of the body vessel.

24. The intravascular filter device of claim 23, wherein said hook region is formed by removing at least a portion of said outer member.

25. The intravascular filter device of claim 23, wherein said hook region comprises a main section, a reversibly bent section, and a pointed tip section.

26. The intravascular filter device of claim 11, wherein at least a portion of said outer member is removed to form one or more zigzag regions along each of said plurality of elongated legs.

27. The intravascular filter device of claim 26, wherein said one or more zigzag regions are longitudinally offset from each other.

28. The intravascular filter device of claim 11, wherein at least a portion of said outer member is electrochemically removed.

29. The intravascular filter device of claim 11, wherein at least a portion of said outer member is chemically removed.

30. The intravascular filter device of claim 11, wherein at least a portion of said outer member is mechanically removed.

31. An intravascular filter device for placement within a body vessel, comprising:

an apical head; and

a plurality of elongated legs each having a proximal end and a distal end, the distal end of each of said plurality of elongated legs being secured to the apical head;

each of said plurality of elongated legs being formed of an elastic inner member and a stiff outer member, wherein a portion of said stiff outer member is removed to form a hook region along each elongated leg.

32. The intravascular filter device of claim 31, wherein said plurality of elongated legs are rod members.

33. The intravascular filter device of claim 31, wherein said plurality of elongated legs are tubular members.

34. The intravascular filter device of claim 31, wherein said plurality of elongated legs are ribbon members.

35. The intravascular filter device of claim 31, wherein said plurality of elongated legs are configured to bend or flex from a substantially straight position to an outswept position when placed within the body vessel.

36. The intravascular filter device of claim 31, wherein at least a portion of the distal end of said stiff outer member is removed.

37. The intravascular filter device of claim 31, wherein said stiff outer member includes a radiopaque material.

38. The intravascular filter device of claim 31, wherein the stiff outer member is formed of a material selected from the group of materials consisting of stainless steel, gold, molybdenum, platinum, titanium, tungsten, Elgiloy, L605, MP35N, Ta-10W, 17-4PH, Aeromet 100, cobalt-chrome alloy, metal glass alloy, and refractory metal alloy.

39. The intravascular filter device of claim 31, wherein said stiff outer member includes a polymeric material.

40. The intravascular filter device of claim 31, wherein said elastic inner member comprises a shape-memory material.

41. The intravascular filter device of claim 31, wherein said elastic inner member comprises a superelastic material.

42. The intravascular filter device of claim 31, wherein said hook region comprises a main section, a reversibly bent section, and a pointed tip section.

43. The intravascular filter device of claim 31, wherein at least a portion of said stiff outer member is removed to form one or more zigzag regions along each of said plurality of elongated legs.

44. The intravascular filter device of claim 43, wherein said one or more zigzag regions are longitudinally offset from each other.

45. The intravascular filter device of claim 31, wherein at least a portion of said stiff outer member is electrochemically removed.

46. The intravascular filter device of claim 31, wherein at least a portion of said stiff outer member is chemically removed.

47. The intravascular filter device of claim 31, wherein at least a portion of said stiff outer member is mechanically removed.

48. An intravascular filter device for placement within a body vessel, comprising:

an apical head; and

a plurality of elongated legs each having a proximal end and a distal end, the distal end of each of said plurality of elongated legs being secured to the apical head;

each of said plurality of elongated legs being formed of an elastic inner member and a stiff outer member, wherein a portion of said stiff outer member is removed to form a hook region and one or more zigzag regions along each elongated leg.

49. An intravascular filter device for placement within a body vessel, comprising:

an apical head having a proximal portion and a distal portion;

a plurality of elongated legs each having a proximal end and a distal end, the distal end of each of said plurality of elongated legs having a reduced diameter portion secured to the proximal portion of the apical head;

each of said plurality of elongated legs being formed of an elastic inner member and a stiff outer member, wherein a portion of said stiff outer member is removed to form a hook region and one or more zigzag regions along the length of each elongated leg, the one or more zigzag regions being longitudinally offset from each other.

50. A composite stent, comprising:

a plurality of threads formed from an outer member comprising a first material, and an inner member comprising a second material different from the first material, wherein the second material is more elastic than the first material; and

at least one flexibility region formed on said composite elongated member, said flexibility region formed by selectively removing a portion of the outer member to expose the inner member.

51. The composite stent of claim 50, wherein said plurality of threads are wire members.

52. The composite stent of claim 50, wherein said plurality of threads are tubular members.

53. The composite stent of claim 50, wherein said plurality of threads are ribbon members.

54. The composite stent of claim 50, wherein the stent is configured to self-expand when deployed in a body vessel.

55. The composite stent of claim 50, wherein said composite stent includes a middle portion and two end portions.

56. The composite stent of claim 55, wherein said at least one flexibility region is located at either of said two end portions.

57. The composite stent of claim 50, wherein said first material includes a radiopaque material.

58. The composite stent of claim 50, wherein the first material is selected from the group of materials consisting of stainless steel, gold, molybdenum, platinum, titanium, tungsten, Elgiloy, L605, MP35N, Ta-10W, 17-4PH, Aeromet 100, cobalt-chrome alloy, cobalt alloy, metal glass alloy, and refractory metal alloy.

59. The composite stent of claim 50, wherein said outer member further includes a polymeric coating.

60. The composite stent of claim 50, wherein said second material comprises a shape-memory material.

61. The composite stent of claim 50, wherein said second material comprises a superelastic material.

62. The composite stent of claim 50, wherein at least a portion of said outer member is electrically removed.

63. The composite stent of claim 50, wherein at least a portion of said outer member is chemically removed.

64. The composite stent of claim 50, wherein at least a portion of said outer member is mechanically removed.

65. The composite medical device of claim 1 wherein the first composite elongated member has a solid cross-section along its length.

66. The composite medical device of claim 1 further comprising a second composite elongated member having a solid inner core formed from the second material, the solid inner core having an outer surface with a perimeter, and an outer member formed from the first material and in contact with all of the perimeter of the outer surface, the second composite elongate member having at least one flexibility region formed by selectively removing a portion of the outer member to expose the solid inner core.

67. The composite medical device of claim 1 wherein the composite medical device has a central longitudinal axis extending from a first end of the composite medical device to a second end of the composite medical device and wherein the first composite elongated member has a central longitudinal axis extending from a first end of the first composite elongated member to a second end of the first composite elongated member, wherein the first end of the composite medical device is in a first direction from the second end of the composite medical device and wherein the first end of the first composite elongated member is in the first direction from the second end of the first composite elongated member and wherein the axis of the first composite elongated member at the first end of the first composite elongated member is offset from the axis of the composite medical device.

68. The composite medical device of claim 67 wherein the axis of the first composite elongated member is at a non-zero angle with respect to the axis of the composite medical device.

69. The composite medical device of claim 66 wherein the first composite elongated member extends in a first direction from a first point of the composite medical

device and wherein the second composite elongated member extends in the first direction from the first end of the composite medical device.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None.